K060737

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510(k) summary, IYE- positioning devices

Sinmed
Radiotherapy products

Sinmed head and shoulder positioning and immobilization systems. (Baseplates)

Date prepared	23-09-05
Submitter	Sinmed BV
Address:	Pasteurstraat 6 2811 DX Reeuwijk Phone: 0031-182-394495 Fax: 0031-182-395014
Contact person:	Caroline de Keijzer (Quality Manager) Leo de Mooy (Technical Director)
Tradename:	-Posifix 1,2,4,5,7 head and neck systems -Positilt head inclination system -Posifix Pediatric -Headsupports -Blocks and wedges -Shouldersupport cushion
Common name:	Head and shoulders immobilization systems.
Classification name:	Linear medical accelerator
Classification:	Class 2 devices, 892.5050 IYE
Intended use:	Fixation and (re)positioning of the head- and neck during radiotherapy and diagnostics.
Substantial Equivalence Device:	The Sinmed head and neck immobilization systems are defined as Substantially Equivalent (SE) to the Bionix 3-Way Head immobilizator; 3Way DeLuxe Reusable Frame, manufactured by Bionix Development corporation. Registration number: 1526854) and cleared by FDA with K933613
Description of the devices: See Sinmed product Catalogue 2006	**Page:** **Product:** 4 -Posifix 1,2,4,5,7 head and neck systems 8 -Positilt head inclination system 4 -Posifix Pediatric 9 -Headsupports 12 -Blocks and wedges 13 -Shouldersupport cushion
Summary of the technological characteristics of your device compared to the predicate device	The Sinmed devices indicated above are all designed to position the head- and neck of a patient for diagnostics and radiotherapy and exactly reposition it several times. All these products can be used in combination with each other to optimize the set-up of a patient. This is exactly the purpose of the Bionix 3-Way Head Immobilizator. The same kind of construction and materials are used to reach this. Products from both companies are used for the same kind of radiotherapy treatments. These products from both companies are really competitive systems.

	Sinmed head and neck immobilization baseplates	Bionix 3-WAY HEAD IMMOBILIZER
Intended use	Fixation and (re)positioning of the head- and neck during radiotherapy and diagnostics	Fixation and (re)positioning of the head- and neck during radiotherapy and diagnostics
Target population.	Radiotherapy patients with tumors in head- and neck area.	Radiotherapy patients with tumors in head- and neck area.
Position of the patient	Lying on a couch in prone or supine position. Shoulders and head are positioned by in a certain position using accessories for an optimized treatment.	*When you're treating tumors in the head and neck region, accurate, reproducible positioning is essential. Our 3-Way Immobilizer works on prone, supine and lateral positioned patients.*
Material	Carbon fiber and acrylic, polyethylene foam. The skin contact materials carbon fiber and acrylic are exactly the same as those used in the predicate device. The cytotoxicity test of the carbon fiber top layer we use is enclosed in Chapter 11. The PE-Foam material is commonly used in radiotherapy, the toxicity report is enclosed in Chapter 11.	Carbon fiber and acrylic version baseplates
Dimensions	Square shaped baseplate which follows the patients contours of head (Posifix -4, -5, -7, Positilt) or head and shoulders (Posifix-1 and -2 and - Pediatric).	Square shaped baseplate which follows the patients contours of the head.
Design / Shape	Flat baseplate on which the thermoplastic mask and various headsupports can be placed. Using the Positilt or other accessories, the baseplate can be inclined to change the position of the head.	Flat baseplate on which the thermoplastic mask and various headsupports can be placed. The baseplate can be inclined to change the position of the head.
Possible adjustments	Head can be lifted or inclined by using the blocks and wedges or the Positilt system.	Head can be tilted or inclined by using the 3-way head immobilizator.
Couchfixation	The Aluminium fixationrails connects the baseplate to the couch. The adjustable aluminium rails can be mounted on all of our baseplates. They allow the baseplate to be locked down in the desired position on the simulator or treatment couch. Depending on the type of couch, one can choose from several mounting brackets.	*The SecureFit bar connects the baseplate to the couch. Our SecureFit bar was designed to index our immobilization devices to the Exact™ Couch for increased accuracy.*
Accessories	Foam headsupports, blocks and wedges, which can position the head for an optimized treatment. Foam Shouldersupport cushion for a better and more comfortable positioning of the patient. . Thermoplastic mask-material which can be placed on the baseplate with plastic profiles.	Headsupports designed for a dedicated treatment can be used on these baseplates. Foam blocks and wedges can be used for a better and more comfortable positioning of the patient. . Thermoplastic mask-material which can be placed on the baseplate with plastic profiles.
Compatibility with the environment and other devices	Can be used on all brands of couches in diagnostic and radiotherapy environment.	*Can be used on an Exact™ couch in diagnostic and radiotherapy environment.*

Brief discussion of the nonclinical tests submitted

The Sinmed described devices above are competitive devices to the device to which substantial equivalence is claimed. Both are designed and used for the same purpose. No comparative investigations are performed, but from clinical experience is known that both products function in the same way.

Sinmed
Radiotherapy products

Sinmed head and shoulders immobilization systems. (Extensionplates)

Date prepared	23-09-05
Submitter	Sinmed BV
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Contact person:	Caroline de Keijzer (Quality Manager) Leo de Mooy (Technical Director)
Tradename:	-Posifix-EXT systems -Shoulderretractor -Couchtop Cover
Common name:	Head and shoulders immobilization systems
Classification name:	Linear medical accelerator
Classification:	Class 2 devices, 892.5050 IYE
Intended use:	Fixation and (re)positioning of the head- and neck during radiotherapy and diagnostics.
Substantial Equivalence Device:	The Sinmed head and neck immobilization systems are defined as Substantially Equivalent (SE) to the Bionix, Versaboard, Model 7040, manufactured by Bionix Development Corporation, Registration number: 1526854) and cleared by FDA with K030051
Description of the devices: See Sinmed product Catalogue 2006	**Page:** **Product:** 8 Posifix-EXT systems 35 Shoulderretractor 5 Couchtop Cover
Summary of the technological characteristics of your device compared to the predicate device	The Sinmed Posifix-EXT system, in combination with the Shoulderretractor and the Couchtopcover, can exactly be compared with the Bionix Versaboard. These products from both companies are intended to position the head- and neck of the patient outside the couch, to optimize the treatment possibilities. The Bionix baseplate is longer and also supports the back and buttocks of the patient. Sinmed has chosen to design a shorter version, and creates this total support by using the couchtop cover. On both systems the mask-material can be placed as well as a choice of headsupports for the positioning of the head. In order to further increase the space around the head of the patient, the shoulders should be suppressed. Sinmed uses a separate Shoulder retractor for this, and Bionix uses the relocatable shoulder suppression system which can be integrated in the baseplate. Both systems are placed and locked on the cranial side of the radiotherapy treatment couch. Both systems are specially developed for use during radiotherapy treatment, and not during diagnostics.

	Sinmed head and neck immobilization baseplates (Extensionplate)	Bionix VERSABOARD, MODEL 7040
Intended use	Fixation and (re)positioning of the head- and neck during radiotherapy, especially IMRT-treatment.	Fixation and (re)positioning of the head- and neck during diagnostics and radiotherapy. *This new board is ideal for IMRT and will solve many of your hard to reach angles and maximize your treatment angles.*
Target population.	Patient with tumors in head- and neck-area, treated with IMRT-techniques	Patient with tumors in head- and neck-area, treated with IMRT-techniques
Special feature in relation to head and shoulder immob. systems.(baseplates)	These extension plates position the head- and shoulders of the patient outside the couch, which enlarges the radiotherapy treatment possibilities.	*It extends off the couch for a broad range of treatment options while improving therapy accuracy.*
Position of the patient	Shoulderretractor suppresses the shoulders for an optimized treatment.	*The optional relocatable shoulder suppression system allows you to comfortably push down the shoulders for better reproducibility.*
Material	Carbon fiber sandwich construction, PE-foam. The skin contact materials carbon fiber is exactly the same as that used in the predicate device. The cytotoxicity test of the carbon fiber top layer we use is enclosed in Chapter 11. The PE-Foam material is commonly used in radiotherapy, the toxicity report is enclosed in Chapter 11.	Carbon fiber sandwich construction..
Dimensions	Baseplate supports the head and shoulders of the patient. When also using the couchtop cover, the patient support is completely flat from head to buttocks.	Baseplate supports the patient from head to buttocks.
Design / Shape	Head- and shoulders are supported by the baseplate and positioned outside the couch.	*Head and shoulders are supported by the baseplate. It extends off the couch for a broad range of treatment options while improving therapy accuracy.*
Possible adjustments	No adjustments possible with the baseplate. Adjustments in positioning of the head- and shoulders can de done by using accessories like different headsupports or the shoulderretractor.	No adjustments possible with the baseplate. Adjustments in positioning of the head- and shoulders can de done by using accessories like different headsupports or the shoulder suppression system.
Couchfixation	Flat baseplate which hooks onto the cranial side of the treatment couch and can be locked. After mounting onto the couch, the construction is fixed with a locking mechanism.	Baseplate can be placed on the couch and attached onto the cranial side.
Accessories	-Thermoplastic mask-material which can be placed on the baseplate with fixation profiles. -Various headsupports designed for a dedicated treatment can be used on this baseplate. -Couchtop Cover to overcome the height difference when also using other baseplates.	-Thermoplastic mask-material which can be placed on the baseplate with plastic profiles. - Headsupports designed for a dedicated treatment can be used on this baseplate.
Compatibility with the environment and other devices	Three types of which each can be placed on a Varian, Siemens or Elekta couch.	Can be placed on a Varian couch

Brief discussion of the nonclinical tests submitted

The Sinmed described devices above are competitive devices to the device to which substantial equivalence is claimed. Both are designed and used for the same purpose. No comparative investigations are performed, but from clinical experience is known that both products function in the same way.

Sinmed
Radiotherapy products

Sinmed lung and thorax immobilization systems

Date prepared	23-09-05
Submitter	Sinmed BV
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Contact person:	Caroline de Keijzer (Quality Manager) Leo de Mooy (Technical Director)
Tradename:	-Thorawedge -Posirest -Posiboard -PET-armsupport
Common name:	Lung and thorax immobilization systems
Classification name:	Linear medical accelerator
Classification:	Class 2 devices, 892.5050 IYE
Intended use: Substantial Equivalence Device:	Positioning the patient for irradiation in the lung- and thorax area. The Sinmed Lung and thorax immobilization systems are defined as Substantially Equivalent (SE) to the MedTec CARBON FIBER BREAST BOARD, manufactured by MED-TEC,INC. (Registration number: 1932738) and cleared by FDA with K974703.
Description of the devices: See Sinmed product Catalogue 2006	**Page:** **Product:** 27 Thorawedge 26 Posirest 23 Posiboard 29 PET-armsupport
Summary of the technological characteristics of your device compared to the predicate device	The Medtec Breastboard is a device intended to position patients undergoing irradiation treatment in the breast- and lung area. This is exactly the same purpose of the Sinmed devices in this group. The patient support of the Medtec Breastboard can be inclined for better treatment. This same inclination of the upper body is also possible with the Sinmed Posiboard and the Thorawedge. To keep the arms out of the treatment area, arms above the head, various armsupports can fixed on the Medtec Breastboard. This fixation of armsupports is also possible on the Sinmed Posiboard. This positioning of the arms above the head to achieve more space around the breast and lung-area is also the exact intended use of the Sinmed Posirest and PET-armsupport and the Thorawedge system. The features of the Medtec Breastboard can all be found in the Sinmed Posiboard. The other three Sinmed lung and thorax immobilization systems are less complicated devices with the same purpose, each with its special features.

	Sinmed Lung and thorax immobilization systems	MedTec Carbon Fiber Breast Board
Intended use	Positioning the patient for irradiation in the lung- and thorax area.	Positioning the patient for irradiation in the lung- and thorax area.
Target population.	Patients with tumors in breast and thorax.	Patients with tumors in breast and thorax
Position of the patient	Supine position, can be inclined, with arms positioned above the head	Supine position, can be inclined, with arms positioned above the head
Material	Carbon fiber sandwich construction, PE-Foam, and acrylic. Only non-metal materials are used, like foam, acrylic and carbon fiber sandwich in the treatment area. The skin contact material carbon fiber is exactly the same as that used in the predicate device. The cytotoxicity test of the carbon fiber top layer we use is enclosed in Chapter 11. The PE-Foam material is commonly used in radiotherapy, the toxicity report is enclosed in Chapter 11. The acrylic material is the same used in the Sinmed head and shoulder positioning and immobilization systems. (baseplates) and is identical to the material used in the predicate device Bionix 3-WAY HEAD IMMOBILIZER.	Carbon-fiber sandwich, there are no metal components in the vital scanning and treatment areas making it even more "CT-friendly";
Dimensions	Optimized dimensions (width) to be CT-scanner compatible	Available in both standard and CT-compatible widths.
Design / Shape	Baseplate, with an aperture for placing various headsupports, Above the head the arms can be placed by using various armsupports.	Baseplate, with an aperture for placing various headsupports, Above the head the arms can be placed by using various armsupports.
Possible adjustments	0-25 degrees inclination possible with Posiboard and Thorawedge. 0 degrees inclination with Posirest and PET-armsupport.	0-25 degrees inclination possible.
Couchfixation	Posirest, Posiboard, PET-armsupport is fixed onto the couch with fixationstrips.	The Medtec Carbon Fiber Breastboard is fixed onto the couch using the MedTec fixation rails.
Accessories	Various headsupports for a comfortable patient positioning. Various armsupports for patient positioning.	Various headsupports for a comfortable patient positioning. Various armsupports for patient positioning.
Compatibility with the environment and other devices	Due to the chosen construction and materials, these products can be used during both diagnostics and radiotherapy.	Due to the chosen construction and materials, these products can be used during both diagnostics and radiotherapy.

Brief discussion of the nonclinical tests submitted

The Sinmed described devices above are competitive devices to the device to which substantial equivalence is claimed. Both are designed and used for the same purpose. No comparative investigations are performed, but from clinical experience is known that both products function in the same way.

Sinmed pelvis and lower extremities immobilization systems (Bellyboard system)

Date prepared	23-09-05
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Contact person:	Caroline de Keijzer (Quality Manager) Leo de Mooy (Technical Director)
Tradename:	Bellyboard Prone thorax support cushion for Bellyboard
Common name:	Pelvis and lower extremities immobilization systems (Bellyboard system)
Classification name:	Linear medical accelerator
Classification:	Class 2 devices, 892.5050 IYE
Intended use:	The Sinmed Bellyboard has been developed in order to reduce the irradiated small bowel volume of gynaecological patients undergoing treatment in the pelvic region.
Substantial Equivalence Device:	The Sinmed Pelvis and lower extremities immobilization systems (Bellyboard) are defined as Substantially Equivalent (SE) to the MedTec Bellyboard, manufactured by MedTec. INC. (Registration number: 1932738) and cleared by FDA with K023293.
Description of the devices: See Sinmed product Catalogue 2006	**Page:** **Product:** 31 Bellyboard 32 Prone thorax support for Bellyboard
Summary of the technological characteristics of your device compared to the predicate device	The Sinmed Bellyboard is substantially equivalent to the MedTec Advanced Belly board System in design, construction, and function. The Sinmed BellyBoard is flat and has a similar, generally rounded rectangular-shaped contour, with areas specifically designed for the head, abdomen, and thighs. The Prone Thorax support cushion has a contoured opening so that the patient may rest his/her head comfortably in the prone position during the treatment process. The abdominal cushion is also designed with an open, contoured cut out region. The patient is positioned over the abdominal cushion such that the belly drops into the cut out region during the radiation therapy session. The Sinmed BellyBoard is constructed in a manner similar to the Advanced Belly board System from Med-Tec, having a hollow thermoformed thermoplastic shell.

	Sinmed Bellyboard system	MedTec Bellyboard
Intended use	*The Sinmed Bellyboard has been developed in order to reduce the irradiated small bowel volume of gynaecological patients undergoing treatment in the pelvic region.*	*The Intermediate Bellyboard features a standard-sized portal for displacement of the small bowel of gynecological patients.*
Target population	Patients with tumors in the lower-abdomen area	Patients with tumors in the lower-abdomen area
Position of the patient	Prone position on this device	Prone position on this device
Material	Carbon fiber sandwich shell construction The skin contact materials carbon fiber is exactly the same as that used in the earlier described predicate device: Bionix VERSABOARD, MODEL 7040. The cytotoxicity test of the carbon fiber top layer we use is enclosed in Chapter 11. PE-Foam: The PE-Foam material is commonly used in radiotherapy, the toxicity report is enclosed in Chapter 11.	Thermoformed plastic shell with a foam core
Dimensions	Thick hollow construction with an aperture to place the belly. Flat top-part for positioning the arms and head.	Thick hollow construction with an aperture to place the belly. Flat top-part for positioning the arms and head.
Design / Shape	Ergonomic design for a comfortable position of the patient. Extra ruler for laser-alignment along the sides of the Bellyboard.	*It features ergonomically correct contours for patient comfort and support, along with millimeter scales for laser alignment.*
Possible adjustments	No adjustments possible, only by using additional cushions like the prone-cushion.	"Interchangeable belly inserts make this Bellyboard system highly versatile and patient- and setup-friendly."
Couchfixation	Can be placed at indexed positions on the couch, using fixation strips.	Indexed Patient Positioning System-compatible, using the MedTec rails
Accessories	Prone cushion for Bellyboard to improve the position on the Bellyboard	Various cushions to optimize the positioning and comfort of the patient
Compatibility with the environment and other devices	This device can be used both in combination with a CT-scanner and an accelerator.	This device can be used both in combination with a CT-scanner and an accelerator.

Brief discussion of the nonclinical tests submitted	The Sinmed described devices above are competitive devices to the device to which substantial equivalence is claimed. Both are designed and used for the same purpose. No comparative investigations are performed, but from clinical experience is known that both products function in the same way.

Sinmed Pelvis and lower extremities immobilization systems

Date prepared	23-09-05
Submitter	Sinmed BV
Address:	Pasteurstraat 6 2811 DX Reeuwijk Phone: 0031-182-394495 Fax: 0031-182-395014
Contact person:	Caroline de Keijzer (Quality Manager) Leo de Mooy (Technical Director)
Tradename:	-Posifix-12 -Multifix -Combifix-system (Baseplate with Kneefix and Feetfix) -Multi Purpose Support cushions
Common name:	**Pelvis and lower extremities immobilization systems**
Classification name:	Linear medical accelerator
Classification:	Class 2 devices, 892.5050 IYE
Intended use: Substantial Equivalence Device:	Positioning of hip and lower extremities of a patient for radiotherapy. The Sinmed Pelvis and lower extremities immobilization systems depicted above are defined as Substantially Equivalent (SE) to the Hip Fixation System manufactured by MedTec, INC. (Registration number: 1932738) and cleared by FDA with K950866.
Description of the devices: See Sinmed product Catalogue 2006	**Page:** **Product:** 36 Posifix-12 36 Multifix 35 Combifix-system (Baseplate with Kneefix and Feetfix) 53 Multi Purpose Support cushions
Summary of the technological characteristics of your device compared to the predicate device	All four products: Posifix-12, Multifix, Combifix-system (Baseplate with Kneefix and Feetfix) and the Multi Purpose Support cushions are products for positioning and immobilization of pelvis and lower extremities. These Sinmed products can be used individually or in combination with each other. The Posifix-12 and the Multifix are baseplates which should be used in combination with thermoplastic masks to fix the pelvis and lower extremities properly. The Medtec Hip Fixation system also uses the thermoplastic masks to fix the hips and extremities of the patient. The Sinmed Combifix is a system with which the pelvis and lower extremities are positioned in the same way as with the Medtec HipFix, but cannot be fixed with Posicast masks. The Sinmed Multi Purpose Support Cushions are actually important accessories of the Sinmed Multifix. With these cushions, the positioning of the extremities can be optimized and fixed with the thermoplastic mask-material.

	Sinmed Pelvis and lower extremities immobilization systems	MedTec Hip Fixation System
Intended use	Positioning of hip and lower extremities of a patient for radiotherapy.	*The HipFix system is a popular choice for hip and pelvis immobilization in either the prone or supine position.*
Target population.	Patients undergoing irradiation treatment in pelvis or lower extremities.	Patients undergoing irradiation treatment in pelvis or lower extremities.
Position of the patient	Supine position (Combifix) Or Prone and supine position. (Posifix-12, Multifix and MultiPurpose Support cushions)	Prone or supine position.
Material	Carbon fiber sandwich or plastic (acrylic and PE-Foam) devices. The skin contact materials carbon fiber is exactly the same as that used in the earlier described predicate device: Bionix VERSABOARD, MODEL 7040. The cytotoxicity test of the carbon fiber top layer we use is enclosed in Chapter 11. PE-Foam: The PE-Foam material is commonly used in radiotherapy, the toxicity report is enclosed in Chapter 11. The acrylic material is the same used in the Sinmed head and shoulder positioning and immobilization systems. (baseplates) and is identical to the material used in the predicate device Bionix 3-WAY HEAD IMMOBILIZER.	*Carbon fiber with plastic*
Design	Baseplate on which the hip and lower extremities of the patient can be positioned by using an individually shaped mask, or using a Kneefix- or Feetfix or a Multi Purpose Support Cushion.	Baseplate on which the hip and lower extremities of the patient can be positioned by using an individually shaped mask. Various cushions can be used to improve the patient positioning.
Possible adjustments	These devices can be adjusted to optimize the fit for the patient. Individual adjustment can be reached by changing distances or using Posicast masks.	These devices can be adjusted to optimize the fit for the patient. Individual adjustment can be reached by changing distances or using individual masks.
Couchfixation	Baseplates can be positioned on the couch on indexed positions.	*Indexed Patient Positioning System-compatible*
Accessories	Repovac vacuum cushions Thermoplastic Posicast mask material Multi Purpose Support Cushion.	Vac-Lok™ vacuum cushions Thermoplastic mask material
Compatibility with the environment and other devices	The -Posifix-12, Multifix, Combifix-system and Multi Purpose Support cushions can be used both in the diagnostic and treatment environment, due to the materials and construction chosen.	The Hip Fixation System can be used both in the diagnostic and treatment environment, due to the materials and construction chosen.

Brief discussion of the nonclinical tests submitted

The Sinmed described devices above are competitive devices to the device to which substantial equivalence is claimed. Both are designed and used for the same purpose. No comparative investigations are performed, but from clinical experience is known that both products function in the same way.

Sinmed
Radiotherapy products

Sinmed Repovac Cushions

Date prepared	23-09-05
Submitter	Sinmed BV
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Contact person:	Caroline de Keijzer (Quality Manager) Leo de Mooy (Technical Director)
Tradename:	Repovac cushions
Common name:	Repovac cushions
Classification name:	Linear medical accelerator
Classification:	Class 2 devices, 892.5050 IYE
Intended use:	Repovac vacuum cushions provide a comfortable, accurate and reproducible patient position throughout the total course of a radiation therapy treatment.
Substantial Equivalence Device:	The Sinmed Repovac cushions depicted above are defined as Substantially Equivalent (SE) to the Vac-Loc immobilization system manufactured by Med-Tec INC. (Registration number: 1932738) and cleared by FDA with K935300.
Description of the devices: See Sinmed product Catalogue 2006	**Page:** **Product:** 45 Repovac cushions
Summary of the technological characteristics of your device compared to the predicate device	Sinmed Repovac cushions, are plastic bags, filled with polystyrene beads and can be made vacuum to follow and keep the contour of a patient. This vacuumbag can be used during the total treatment to achieve an identical patient set-up every time. This is exactly the intended use and functioning of the MedTec vacuum cushions. Differences can be found in shape, color and top layer material.

	Sinmed Repovac cushions	MedTec Vac-Lok Immobilization System
Intended use	Repovac vacuum cushions provide a comfortable, accurate and reproducible patient position throughout the total course of a radiation therapy treatment.	*When a complete vacuum is drawn through the quick-release valve, the cushion becomes a rigid and comfortable mold, offering accurate reproducibility throughout the course of simulation and treatment.*
Target population.	Radiotherapy patients, all kinds of treatments	Radiotherapy patients, all kinds of treatments
Position of the patient	*The cushion forms a rigid mould of the patient by a vacuum that is drawn following the patient's contours. The quick-release valve and the airtight polyurethane bag allow the mould to maintain its shape over a long period of time. This ensures a reproducible patient set-up through imaging, simulation and treatment of the patient.*	*While semi-deflated, the cushion is easily molded around a patient's anatomical contours. When a complete vacuum is drawn through the quick-release valve, the cushion becomes a rigid and comfortable mould, offering accurate reproducibility throughout the course of simulation and treatment.*
Material	Polyurethane sheets with Polystyrene micropellets. The skin contact materials are exactly the same as those used in the predicate device.	*A rugged clear urethane and an extra-durable nylon-reinforced blue urethane material that resists punctures. Rugged, radiotranslucent cushions are filled with tiny polystyrene beads.*
Dimensions	Different dimensions available, square or a special shape for a special purpose.	Different dimensions available, square or a special shape for a special purpose.
Design / Shape	Various dimensions and shapes available for various purposes.	Various dimensions and shapes available for various purposes.
Possible adjustments	Cushion follows the individual contours of the patients.	Cushion follows the individual contours of the patients.
Couchfixation	Cushions cannot be fixed onto the couch.	Cushions cannot be fixed onto the couch.
Accessories	Vacuum pump, both manual and electrical "Moulding guides" to facilitate moulding of the cushion	Electrical Vacuum pump "Helping hands" to facilitate moulding of the cushion
Compatibility with the environment and other devices	Some Vacuumcushions are specially designed for use on Sinmed positioning devices to improve the positioning and comfort of the patient.	Some Vacuumcushions are specially designed for use on Medtec positioning devices to improve the comfort and positioning of the patient.

Brief discussion of the nonclinical tests submitted

The Sinmed described devices above are competitive devices to the device to which substantial equivalence is claimed. Both are designed and used for the same purpose. No comparative investigations are performed, but from clinical experience is known that both products function in the same way.

Sinmed Posicast immobilization systems

Date prepared	23-09-05
Submitter	Sinmed BV
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Contact person:	Caroline de Keijzer (Quality Manager) Leo de Mooy (Technical Director)
Tradename:	Posicast
Common name:	Posicast immobilization systems
Classification name:	Linear medical accelerator
Classification:	Class 2 devices, 892.5050 IYE
Intended use: Substantial Equivalence Device:	Immobilization of a patient by using a thermoplastic mask. The Sinmed POSICAST IMMOBILIZATION SYSTEM depicted above is defined as Substantially Equivalent (SE) to the Posicast Immobilization SYSTEM registered by Huestis Machine Corporation. (Registration number: 1219183) and cleared by FDA with K926187. The following table compares the Sinmed POSICAST IMMOBILIZATION SYSTEM and the predicate device. Huestis has registered this product when they were our representative in 1992. The distribution of Sinmed Posicast will be through another American company. Therefore we want to register this product under our own name. So the product we want to register is exactly the same as the material Huestis has registered in 1992.
Description of the devices: See Sinmed product Catalogue 2006	Page: 14-21 Product: Posicast
Summary of the technological characteristics of your device compared to the predicate device	The 510(k) for Posicast has been approved by the FDA in 1994 (K926187). The material, intended use etc. have not changed since then. Therefore a comparison seems to be not necessary.

	Sinmed POSICAST IMMOBILIZATION SYSTEM	Huestis Posicast Immobilization SYSTEM
Intended use	Exactly the same	Exactly the same
Target population.	"	"
Position of the patient	"	"
Material	"	"
Dimensions		
Design / Shape		
Possible adjustments		
Couchfixation	"	"
Accessories	"	"
Compatibility with the environment and other devices		"

Brief discussion of the nonclinical tests submitted	Both the Sinmed Posicast immobilization system and the Huestis Posicast Immobilization SYSTEM are exactly the same. Therefore no clinical comparative tests are necessary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2006

Sinmed Holding Internation B.V.
% Ms. Patricia L. Murphy
Eastern Regional Manager,
Medical Certification
KEMA Quality B.V.
US Medical Operations
4377 County Line Road
CHALFONT PA 18914

Re: K060737
Trade/Device Name: Sinmed Immobilization Systems (Head and Shoulder, Lung and Thorax, Pelvis and Lower Extremities, and Posicast) and Sinmed Repovac Cushions
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 16, 2006
Received: March 20, 2006

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): - K060737

Device Name:

1 -Posifix 1,2,4,5,7 -head and neck systems
-Positilt head inclination system
-Posifix Pediatric
-Headsupports
-Blocks and wedges
-Shouldersupport cushion

2 -Posifix-EXT systems
-Shoulderretractor
-Couchtop cover

3 -Thorawedge
-Posirest
-Posiboard
-PET-armsupport

4 -Bellyboard
-Prone thorax support cushion for Bellyboard

5 -Posifix-12
-Multifix
-Combifix-system (Baseplate with Kneefix and Feetfix)
-Multi Purpose Support cushion

6 -Repovac cushions

7 -Posicast

Indications For Use:

1 Fixation and (re)positioning of the head- and neck area of the patient during radiotherapy and diagnostics.

2 Fixation and (re)positioning of the head- and neck area of the patient during radiotherapy and diagnostics.

3 Positioning of the lung- and thorax area of the patient during radiotherapy and diagnostics.

4 Positioning of the lower abdomen of a patient during radiotherapy and diagnostics.

5 Positioning of hip and lower extremities of a patient during radiotherapy and diagnostics.

6 Fixation and (re)positioning of the patient during radiotherapy and diagnostics.

7 Fixation and (re)positioning of the patient during radiotherapy and diagnostics.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Sinmed (6030455) IYE-Positioning devices

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060737